Region 2 Caribbean Environmental Protection Division
Multimedia Permits and Compliance Branch
Air Protection Team

CAA Inspection Report

Inspection Date: January 17, 2023

Facility Name: Customed Inc.

Facility Address: Igualdad Street Final #7, Fajardo, Puerto Rico

EPA Lead Inspector: Alex Rivera, Enforcement Officer, 787-977-5845, Rivera.Alex@epa.gov

EPA Asst. Inspector: Gloria Díaz-Galarza, Inspector In-Training, 787-977-5882, Diaz-Galarza.Gloria@epa.gov

Facility Contact: Ruben Martínez, QA/RA Director and Management Representative, 787-622-5151 ext. 7634, ruben.martinez@prhospital.com

This was a Clean Air Act ("CAA") compliance inspection of Customed Inc. ("Customed" or "facility"), by the United States Environmental Protection Agency ("EPA"). EPA's Alex Rivera led the inspection with the assistance of EPA's Gloria Díaz-Galarza. The purpose was to evaluate the facility compliance with the below listed regulatory programs:

Permitted Regulatory Program(s) Reviewed:

1. Operating permit PFE-RH-27-1021-0523-I-II-O ("Permit"), issued on March 25, 2022
2. General Provisions – 40 CFR Part 63 Subpart A
3. Ethylene Oxide Emissions Standards for Sterilization Facilities – 40 CFR Part 63, Subpart O ("NESHAP Subpart O")

This report is a summary of observations and information gathered from the facility at the time of the inspection. The information provided does not constitute a final decision on compliance with CAA regulations or applicable permits, nor is it meant to be a comprehensive summary of all activities and processes conducted at the facility.

1. Inspection Summary

Opening Meeting

Mr. Rivera and Ms. Díaz-Galarza ("the inspectors") arrived at the facility administrative building at 11:00 AM. The on-site inspection was announced to Customed on Friday January 13, 2023. The inspectors presented inspection credentials and were received by Mr. Ruben Martínez (QA/RA Director and Management Representative). Mr. Martínez escorted the inspectors to a

conference room within the facility administrative building. Inspector Rivera explained that the purpose of the inspection was to evaluate compliance with facility Permit and the NESHAP Subpart O.

Mr. Rivera explained that the inspection would consist generally of a records review, a question-and-answer session, and a facility walkthrough. After concluding the opening meeting, the inspectors began with the inspection questionnaire. The following is a summary of the information provided:

Questionnaire Discussion:

Facility General Information

According to Mr. Martínez, the facility started operations in 1989. However, Customed started to conduct sterilization activities using ethylene oxide ("EtO") in 2005. Before 2005, the facility contracted the sterilization services from another sterilizing facility in Salinas, PR. Customed is a subsidiary of Puerto Rico Hospital Supply, Inc. According to Mr. Martínez, the facility it's a private company in the health care industry providing medical equipment and devices, safety products, and daily protective essentials to hospitals, clinics, and other front line health service providers. Mr. Martínez stated that the facility is classified by the U.S. Food and Drug Administration ("FDA") as a Convenience Surgical Kit Manufacturer. Mr. Martínez provided a description of the manufacturing process conducted at the facility and confirmed that the facility manufacturing process has been the same since 1989. The following summarize the manufacturing process flow: a) components are evaluated and approved; b) components are purchased; c) then surgical packs are assembled using approved components; d) after assembly, packaged products are heat sealed and; e) final sterilization process is added when required by a customer. Mr. Martínez added that when sterilization is required, products are sterilized using EtO. Mr. Martínez stated that manufactures surgical kits for 10 different families of surgeries and provide service to approximately 50 hospitals and clinics.

Mr. Martínez informed that the facility has four (4) total buildings. Two (2) buildings (Building #1 and Building #2) located across the street and next to CVS's Pharmacy Building, which are used as warehouse and assembly operations and two (2) additional buildings (Building #3 and Building #4), that are for administrative purposes and sterilization. Mr. Martínez added that the facility has 48 employees, and that four (4) employees work at the sterilization process. Two (2) assigned to the sterilization process and two (2) to the quality control area.

Operations

Mr. Martínez confirmed that the facility operates Monday through Friday, from 7:00 AM to 5:00 PM. According to Mr. Martínez, the sterilization area has a different operating schedule and that during days when a sterilization cycle is processed, the working hours are from 5:00 AM to 3:30 PM, on days when no sterilization cycle is scheduled the hours are from 5:00 AM to 1:30 PM.

Mr. Martínez indicated that the facility completes around 130-140 cycles per year and provided copies of the monthly cycles that are completed in a yearly basis from 2019-2022. Mr. Martínez also provided a copy of the annual EtO consumption for 2022, and indicated that the facility uses around 8,000 pounds of EtO per year and that Customed restricts the use of EtO to less than

10,000 pounds per year. Mr. Martínez added that the company sterilization cycle uses a fixed amount of 62 pounds of EtO per cycle.

According to Mr. Martínez, the facility sterilization process consists of three (3) phases: 1) a preconditioning phase which last a minimum of 12 hours or up to 14-15 hrs, and where the product is exposed to the desired humidity and temperature; 2) a sterilization phase that has a duration of 8.5 hours, including an EtO exposure of 3 hours or 180 minutes; and 3) an aeration phase that has a duration of a minimum of 24 hours.

According to Mr. Martínez, the facility uses three (3) different types of packaging systems: 1) breather bags (polyethylene material/Tyvek® material); 2) Tray (high impact polystyrene/Tyvek® material); 3) Tray (soft polyethylene/Tyvek® material). All three (3) packaging configurations use the same sterilization cycle, and all require a minimum aeration time of 24 hours. Mr. Martínez added that these special packaging configurations has a specific porosity that allows for easy EtO access and removal, thus ensuring the product sterilization, proper removal of EtO, and the product integrity.

Mr. Martínez provided a description of the facility post-sterilization and validation processes. Mr. Martínez clarified that not all product or components managed at the facility requires to be sterilized, some components are received already certified as sterilized. Post-sterilization activities include the inspection of components, product assembly and packaging. Final product can either go from the facility directly to hospitals or to Puerto Rico Hospital Supply Inc. distribution center in Rio Grande. Mr. Martínez added that every two (2) years the facility validation processes are very rigorous and involves a series of testing to determine the product EtO residuals, this for the purpose of guaranteeing that the sterilization cycle is efficient in sterilizing the product and in removing the EtO from its packaging.

Mr. Martínez provided an explanation about how EtO emission varies throughout a day when a sterilization cycle is performed. Chamber emissions treated by the wet scrubber system occur only during nitrogen and air wash phases for approximately 3 hours per day. Chamber exhaust vent emissions are released to atmosphere for approximately 1 hour. Aeration room emissions are treated continuously for a 24-hour period following each sterilization cycle. Mr. Martínez added that the facility uses 3M™ batch monitors[1] once per quarter for 8 consecutive hours and its results are provided to EPA and the PR Department of Natural and Environmental Resources (DNER) as part of the NESHAP Subpart O semi-annual compliance reports.

Mr. Martínez informed that the facility has a wet scrubber and dry scrubber systems to treat the EtO emissions and demonstrate compliance with the NESHAP Subpart O. Both units were installed in 2004 and its initial performance test was conducted in 2005. No changes to these units have been performed since then. The facility has one (1) sterilization chamber (1,212 cubic feet/9 pallets), one (1) pre-conditioning room and one (1) aeration room (1,040 square feet).

[1] https://www.3m.com/3M/en_US/p/d/v101276205/ - Example of 3M™ Ethylene Oxide Monitor 3551+B

According to Mr. Martínez the facility does not have any plans for expansion. The following is a summary of the description given by Mr. Martínez about the facility EtO emission units:

Wet Scrubber System – The wet scrubber system starts as soon as the EtO sterilization process begins the washing process (after the sterilization exposure phase is completed). The chamber's EtO gases enter directly to the bottom of the Scrubber Tower and flows upward through the packing material designed to provide intimate contact between the gas and the circulating solution (sulfuric acid and water). The acid water solution is introduced at the top of the Scrubber Tower and a spray and flows over the highly reticulated packing material exiting at the base/bottom of the tower. The recirculating acid solution flows by gravity into reactor tank #1. From reactor tank #1, solution flows by gravity into reactor #2. Each tank has a nominal volume of 2,000 gallons.

Acid water and water solution (scrubber liquor) is drawn from reactor tank #2 by recirculating pump and is delivered back to the top of the Scrubber Tower. During this process the ethylene oxide is converted to ethylene glycol in the reactor/storage tanks. The solution continuously recirculates through the scrubber system loop. The ethylene glycol solution generated from the washing/scrubber tower is considered saturated when reactor tank #2 level reaches the 62- and 13/16-inches mark. At this level, the ethylene glycol solution concentration was determined to be 30%. The scrubber liquor level is recorded once per week.

The correlation between reactor tank #2 level and ethylene glycol concentration was established during initial scrubber/process validation**.** At the 30% concentration, the ethylene oxide absorption is decreased. The facility needs to pump/transfer the liquid (ethylene glycol) from Reactor Tanks (#1 and #2) to a neutralization tank, and then add sodium hydroxide into the neutralization tank to adjust its pH.

Solution's pH level needs to be adjusted per local and federal regulations. The pH level must be adjusted to around 7 prior to final disposal. After saturated ethylene glycol is removed from reactor tanks #1 and #2, a fresh sulfuric acid/water solution is added to the Scrubber System. The neutralized old solution is discarded by an approved/authorized facility.

Dry Scrubber System - Aeration room vent gas is continuously treated with an AAT DR-90 dry bed reactor. It is a two-bed system. A forced draft fan removes air from the aeration room and feeds the lower bed of the AAT dry bed reactor. Air travels through the lower bed then through the upper bed before release to atmosphere. The reactive bed material is a proprietary characterized by small yellow beads. The beads react with EO to form a polymer that binds with the beads, thus removing EtO from the air stream. The dry scrubber system media is replaced approximately every two (2) years. The dry scrubber system outlet EtO concentration is monitored to be less than 1 ppm. The facility monitors the dry scrubber system outlet EtO concentration quarterly; three (3) times by sample bag sent to analytical laboratory and one (1) per year a performance test is conducted on-site as required by DNER.

Records

Mr. Martínez provided a copy of the facility 2022 compliance annual report. Inspector Rivera acknowledged having copies of all NESHAP Subpart O semi-annual reports and informed Mr. Martínez that if needed, further documents and information might be requested as part of the post-inspection process.

Other Information

Mr. Martínez informed that the facility uses 3M™ organic diffusion monitors[2] to measure the employees EtO exposure and the two (2) employees that work on the sterilization process are required to wear a self-contained breathing apparatus (SCBA) while conducting activities involving a potential exposure to EtO. Mr. Martínez stated that sterilization employees are trained on all sterilization procedures and that training includes all aspects of EtO sterilization process, including, safety, personal protective equipment (PPE) and other company required procedures. Mr. Martínez added that employees are required to be trained annually and that whenever a sterilization procedure is revised, the affected employees are trained prior to implement any changes.

Mr. Martínez indicated that the facility has three (3) EtO sensors at the facility. According to Mr. Martínez, these EtO sensors are in the sterilization tank storage area, the wet scrubber area and the sterilization chamber room. The monitors at the scrubber area and sterilization chamber room triggers an alarm in the control room. The sterilization tank room is a local alarm visible in that area.

According to Mr. Martínez sterilized product is hold in the facility warehouse prior to be shipped out for approximately 8 days or 96 hours. Mr. Martínez confirmed that no warehouse areas are kept under negative pressure, the only area under negative pressure is the aeration room.

Potential Emission Control Improvements

Mr. Martínez informed that Customed is evaluating installing two (2) dry scrubbers in series to treat the chamber exhaust vent emissions, which are currently allowed to be emitted to the atmosphere by the NESHAP Subpart O. Mr. Martínez showed copies of the facility communication with the dry scrubber system manufacturer requesting quotes.

2. Facility Walkthrough

The inspectors and Mr. Martínez began the walkthrough at around 2:55 PM. The following is a summary of the main observations and information provided by Mr. Martínez during the walkthrough:

- The facility has a total of three (3) emergency power engines.
- The facility has a detailed emergency evacuation map offering details about the sterilization building layout and rooms.

[2] https://multimedia.3m.com/mws/media/211130O/3m-organic-vapor-diffusion-monitor-3500-3510-and-3520-3530-brochure.pdf - Example of 3M organic vapor diffusion monitors

- The facility only has two (2) sterilization recipes, one for product sterilization and the other for validation purposes.
- Each sterilization lot has a total of 32 biological indicators (3-4 biological indicators per pallet).
- Pallets are prepared and entered in a pre-conditioning room and exposed to a predetermined humidity and temperature for no less than 12 hours (approximately 12-14 hours) prior to place the pallets to the sterilization chamber.
- The facility has one (1) Vacudyne[3] chamber of a capacity of 9 pallets.
- The facility has one (1) Fulton fuel-fired steam boiler model ICS-50 that is used to generate the necessary steam injected to the sterilization chamber.
- The sterilization area has a control room that is automated and uses an Antares K-Series sterilizer control system. The room has a battery backup that allows the facility to maintain the system in operation for at least 1 hour.
- The sterilization area operators use SCBA protection to access the sterilization chambers and aeration rooms while loading and retrieving product.
- The sterilization building warehouse staging area is kept under a predetermined temperature and humidity.
- Two (2) employees work at the sterilization area and two (2) work at the post-sterilization quality control area.
- The sterilization chamber has a chamber exhaust vent pump that is activated once the chamber door is opened. The chamber exhaust vent air is conveyed and exhausted to the atmosphere.
- The aeration room is kept at 125°F. It has one (1) blower to recirculate air and heat the room and to convey air to the dry scrubber system. The room is kept under negative pressure.
- The wet scrubber system glycol level was approximately 53 inches at the time of the walkthrough.
- The facility sterilization cycles usually start at 5:30 AM and ends around 2:30 PM.

At approximately 4:00 PM, the inspectors completed the walkthrough and were escorted by Mr. Martínez to the administrative building conference room.

3. Closing Meeting

At approximately 4:00 PM, the inspectors returned to the conference room for a closing conference. During the closing conference, the inspectors acknowledged Mr. Martínez professionalism and flexibility in accommodating the inspection on short notice. The following is a summary of the closing meeting conversation:

- Inspector Rivera informed Mr. Martínez about EPA's community outreach activity to be held in the community surrounding the facility around the end of the month of January 2023 and that Customed and its employees are welcome to participate. Inspector Rivera

[3] https://www.vacudyne.com/products/eo-sterilizers

informed that the activity was going to be like other activities EPA has conducted in other communities near sterilizers in Puerto Rico, such as in Añasco and Salinas.

- Inspector Rivera requested copies of the facility emergency evacuation map and examples of the facility Antares system[4].

Inspector Rivera expressed gratitude for all the assistance provided during the inspection and all the cooperation to provide the information needed to complete the inspection. The inspectors concluded the inspection at 4:25 PM.

Inspection Report Sign-Off

Lead Inspector's Name: Alex Rivera

ALEX RIVERA

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Assisting Inspector's Name: Gloria Díaz-Galarza

GLORIA DIAZ-GALARZA

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Supervisor's Name: Nancy Rodríguez

NANCY RODRIGUEZ

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[4] Customed's Ruben Martínez submitted the requested information to EPA's Alex Rivera via email on January 18, 2023.